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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/389,565	09/03/1999	DAVID M. NEVILLE, JR.	14028.0290	5574

  

36339 7590 07/02/2007 NATIONAL INSTITUTE OF HEALTH C/O NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30303	
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EXAMINER
EWOLDT, GERALD R

  

ART UNIT	PAPER NUMBER
1644	

  

MAIL DATE	DELIVERY MODE
07/02/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/389,565	NEVILLE, JR. ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-33, 37, 39, 44-49 and 51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-33, 37, 39 and 44-47 is/are allowed.
- 6) ☒ Claim(s) 48, 49 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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#### DETAILED ACTION

1. Applicant's amendments and remarks filed 5/15/07 are acknowledged.
2. Claims 31-33, 37, 39, 44-49, and 51 are pending and being acted upon.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 48, 49, and 51 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

The immunotoxin of Claim 48 comprising a truncated diphtheria toxin moiety ... wherein the truncated toxin moiety bypasses the inhibitory effect of pre-existing anti-diphtheria toxin antibodies, is not disclosed in the specification.

Applicant indicates that, "Applicants have again amended claim 48 to track the language of the specification on page 40, lines 28-32 which describes a truncated toxin moiety that bypasses the inhibitory effect of pre-existing anti-diphtheria antibodies".

A review of page 40, lines 28-32 discloses, "A DT point-mutant, a truncation mutant and DT-subfragments were used in an attempt to neutralize the anti-DT effect in human sera. Based on the neutralization data, a single-chain immunotoxin was constructed with a C-terminal deletion mutant of DT which is expected to bypass the inhibitory effect of the pre-existing anti-DT antibodies". This cite comprises part of Example 9, wherein at page 40, lines 28-32 the specific "C-terminal deletion mutant of DT" is not disclosed. This example, wherein a *single, undefined* construct is disclosed, cannot support the generic immunotoxin of the instant claims.

Applicant cites original Claims 4-7.

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Original Claims 4-7 do not recite the new limitation of a truncated toxin moiety which bypasses the inhibitory effect of pre-existing anti-diphtheria toxin antibodies. This limitation is disclosed only at page 40 as set forth in the description of the single, undefined construct of Example 9.

Applicant's arguments, filed 5/15/07, have been fully considered but they are not persuasive. Applicant argues that Example 9 supports a genus of diphtheria toxin truncation mutants, again citing page 40, lines 28-32.

The title of the example is "An anti-CD3 single-chain immunotoxin with a truncated diphtheria toxin avoids inhibition by pre-existing antibodies in human blood" (emphasis added). Nothing disclosed in the example indicates a description of more than the single antibody of the title. Further the lines cited by Applicant also disclose a single mutant, i.e., "...a truncation mutant... (emphasis added).

Applicant argues that Claim 45 describes 3 species of the genus of Claim 48.

There is no disclosure that the immunotoxins of Claim 45 (truncations of 145, 150, and 152 C-terminal amino acids of diphtheria toxin) are species of the genus of immunotoxins of Claim 48. Further, even if they are, there is no disclosure that they are representative of all of the species of immunotoxins that would "bypass the inhibitory effect of pre-existing anti-diphtheria toxin antibodies".

Applicant cites pages 9 and 39 of the specification in support.

First note that the cite at page 39 of the specification falls within Example 9 (which discloses a single construct). Regardless, neither page 9 nor page 39 disclose the genus of immunotoxins that "bypass the inhibitory effect of pre-existing anti-diphtheria toxin antibodies" of Claim 48.

Applicant cites a reading of the specification as a whole.

The specification as a whole does not support the genus of immunotoxins of Claim 48 that comprise UCHT-1 and a truncated diphtheria toxin that "bypasses the inhibitory effect of pre-existing anti-diphtheria toxin antibodies".

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5. Claims 31-33, 37, 39, and 44-47 are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

8. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



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